DETAILED ACTION

1. The amendment filed March 5, 2008 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claims 1, 8-17, 19 and 28-39 are pending.

3. Claims 28-38 have been withdrawn from consideration.

4. Claims 1, 8-17, 19 and 39 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 8-17, 19 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite because the new limitation of "adapted for adsorption in the digestive tract" is unclear. It is unclear what adaptations can be used to achieve this purpose. Furthermore, claims 1 and 39 now state "...a nutritionally effective amount of six or more essential saccharides adapted for adsorption in the digestive tract." The examiner's interpretation of this limitation is that the saccharides are "adapted for adsorption" in the digestive tract but it is unclear if the other ingredients are also "adapted for adsorption." Applicant's arguments regarding the 103 rejection based on Gohlke, Donzis and McAnalley indicate that the applicant intends for the entire composition to be "adapted for adsorption." As discussed below, the specification does not provide guidance on this point. Thus, the claims are

indefinite because it is unclear if all of the ingredients are "adapted for adsorption in the digestive tract" and how to perform these "adaptations."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 8-17, 19 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to include the limitation "adapted for adsorption in the digestive tract." This limitation is considered to add new matter into the specification. As discussed above, it is unclear if this limitation is referring to adaptation of the entire composition or of only the saccharides. In either instance, there is considered to be a lack of support in the specification for this new amendment. The specification does not teach how to "adapt" any of the ingredients for adsorption into the digestive tract. In fact, the specification discusses at length that the composition is in a mucosal delivery format that allows for the ingredients to be absorbed through the lining of the oral cavity rather than in the digestive tract (see paragraphs 51, 52). Thus, the specification does not teach how to make a composition that is adapted for adsorption in the digestive tract; therefore, this new limitation introduces new matter into the claims.

Claim Rejections - 35 USC § 103

7. Claims 1, 8-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donzis (US Pat. No. 5,576,015), Paul (US Pat. No. 5,531,989), Plaut (WO 97/05884) and McAnalley (WO 98/06418) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Paul teaches away from the use of colostrum by using isolated and purified immunoglobulins rather than colostrum. However, Paul does not teach that colostrum itself is not effective. The BPAI concluded in the September 22, 2006 decision that it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the colostrum of the infant formulas of Plaut comprising immunoglobulins, for the immunoglobulins derived from bovine colostrum of Paul into the composition of Paul, with the expectation that the colostrum incorporating natural immunoglobulins (Plaut) would function in a similar manner to the immunoglobulins derived from colostrum described in both Plaut and Paul. The motivation stems from the expected benefit of stimulating the immune system, enhancement of resistance to diseases, both viral and bacterial, and enhancement of growth rate, survival rate and feed efficiency, and promotion of gastrointestinal health which are advantages to using colostrum described in Plaut. Furthermore, an artisan would expect that use of colostrum would prevent the artisan from having to isolate and purify the immunoglobulins as taught by Paul.

Applicant also argues that neither Plaut nor Paul include beta-glucan in the composition. Applicant argues that if Plaut or Paul had wished to include beta-glucan in the composition they would have done so. Applicant appears to be arguing that any type of 103 rejection is improper. Applicant appears to be arguing that if the reference is not an anticipatory reference then a rejection should not be applied. However, this is improper. As long as the factors providing proper motivation have been met, a combination of references is appropriate. In this case, Donzis describes that glucan extracted from yeast cell walls is a potent stimulator of the immune system (Column 1, lines 20-21) and recommends that beta (1,3) glucans be incorporated as a nutritional supplement for a broad spectrum of animals and humans. Column 1, lines 52-67. Donzis indicates that beta glucan strongly enhances resistance to diseases, both viral and bacterial, and enhances growth rate, survival rate and feed efficiency. Column 3, lines 15-27. It would have been further obvious to incorporate the yeast cell wall beta-glucan, an insoluble fiber, of the nutritional supplement of Donzis, into the immunoglobulin and fiber nutritional supplement of Paul with the expected benefit of stimulating the immune system, enhancement of resistance to diseases, both viral and bacterial, and enhancement of growth rate, survival rate and feed efficiency, and promotion of gastrointestinal health. Donzis specifically states that yeast extract beta glucan can be combined with conventional nutritional materials to create a more supportive environment within the body to assist the primary killing action of conventional agents and thereby enhance significantly growth and survival. Column 5, lines 50-60. Thus, since there is proper motivation for the combination of the teachings of Donzis with those of Paul and Plaut, it is considered obvious to combine beta-glucan, citrus pectin, lactoferrin, and colostrum together into a single composition.

Applicant also argues that Donzis does not teach the use of six or more essential saccharides. However, the previous Office action did not state that Donzis teaches this limitation. McAnalley was cited to provide motivation for the combination of the claimed saccharides into the composition. Paul teaches the use of saccharides in the composition but does not teach six or more "essential" saccharides. McAnalley teaches nutritional compositions comprising essential saccharides. The compositions can contain at least six essential saccharides and are derived from the same sources claimed by applicant (see pages 7 and 8). The reference teaches that these saccharide compositions are superior to other types of saccharide dietary supplements because "by providing these essential saccharides, the mammal's body does not have to spend energy unnecessarily catabolizing these essential saccharides which allows for energy to be spent in other ways" such as by increasing the health and immune system of the patient (see page 7). Thus, McAnalley shows that it was known in the art at the time of the invention that using essential saccharides in the composition would produce better results that using non-essential saccharides. Therefore, an artisan of ordinary skill would then reasonably expect that the formulation of colostrum, beta-glucan, citrus pectin and taught by Donzis, Paul, and Plaut could be improved by substituting the saccharides for the essential saccharides of McAnalley. This reasonable expectation of success would motivate the artisan to modify the composition taught by Donzis, Paul, and Plaut to include essential saccharides as taught by McAnalley.

In regards to the new limitation that the composition is "adapted for adsorption in the digestive tract," as best as this limitation is understood, the prior art also meets this limitation

because the prior art composition is ingested which would allow the ingredients to travel to the digestive tracts for digestion.

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655